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**Positioning Children's Voice in Clinical Trials Research: A new Model for
Planning, Collaboration and Reflection**

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Abstract

Following the United Nations Convention on the Rights of the Child (1989), there has been considerable growth in research with children about health and services that affect them. Creative methods to engage with children have also been developed. One area where progress has been slower is the inclusion of children's perspectives in qualitative research in the context of clinical trials or feasibility studies. Addressing this gap, this article discusses experiences of, and reflections on, the process of researching children's views as part of a clinical feasibility study. The article considers what worked well and highlights remaining dilemmas. A new continuum of children's engagement in research is presented, designed to assist researchers to make explicit the contingent demands on their research, and to suggest a range of techniques from within the broader fields of health, childhood studies and education research that could be used to forward qualitative research in clinical contexts.

Keywords

children, illness and disease, lived experience, methodology, research design

Background and Introduction

Within the academic fields of early years, sociology of childhood, childhood studies and education, there has been a long tradition of research with children. Guided by the United Nations Convention on the Rights of the Child (UNCRC) (United Nations, 1989), researchers from the domains of sociology of childhood (Prout & James, 1997), early years and inclusive education have developed approaches to prioritize children's voice from a children's rights perspective. In particular, Article 12 of UNCRC sets out that children have the right to have their views respected once they are capable of forming them. In response to this, research methods have prioritized building interactive relationships with children (Nind & Hewett, 2006), consultation (Aubery & Dahl, 2006; Porter, Daniels, Georgeson, Hacker, Gallop, Feiler, Tarleton & Watson, 2008; Porter, Daniels, Martin, Hacker, Feiler & Georgeson, 2010), finding ways beyond talk to seek children's views, (Alderson, Hawthorne & Killen, 2005; Bae, 2010; Clark & Moss, 2012) and engaging children in setting research agendas, as well as directing the methods (Kellett, 2010 & 2011; Bradbury-Jones & Taylor, 2015) whilst attempting to avoid 'othering' children in the research relationship (Lahman 2008).

Within the field of health care research, however, progress has been slower. Fears relating to the ability of children to understand and communicate complex issues has traditionally led to the seeking of 'proxy' adult perspectives (especially parents) in qualitative research, instead of direct engagement with children themselves (Huang, O'Connor, Ke, & Lee, 2014). This may have been exacerbated by a traditional preference within health research for the use of quantitative clinical studies, such as randomized controlled trials. Important for rigorously testing the efficacy of treatments and procedures, such approaches are used to identify causal relations and are characterized by the strict control of variables and confounding factors, through the use of standard operating procedures and protocols (Lewin, Glenton, & Oxman, 2009). Within this paradigm, the more emergent, flexible and nuanced

approach of qualitative research – particularly that with children and young people, may be viewed as beset with pitfalls (Cooper, O’Cathain, Hind, Adamson, Lawton & Baird, 2014).

Nevertheless, in the decades since the UNCRC, the picture has gradually changed. There is a growing body of qualitative health research with children and young people, in which researchers have sought perspectives and personal experiences of illness and treatment (e.g. Horstman, Aldiss, Richardson, & Gibson, 2008), views on broader concepts related to health and wellbeing (e.g. Irwin & Johnson, 2005) and input into the design and delivery of services via Patient and Public Involvement (PPI) initiatives such as youth councils (e.g. Coad, Flay, Aspinall, Bilverstone, Coxhead & Hones, 2008). In the UK, this has been reinforced by an increased policy focus on the importance of incorporating children’s interests and views into the design of health and care services that affect them (for a discussion, see Weil, Lemer, Webb, & Hargreaves, 2015), with engagement with children and young people now seen as the ‘gold standard’. Whilst a recent report (Office of the Children’s Commissioner, 2013) suggests that children’s participation is not yet embedded in health decision making, there has been undeniable progress in research with children and the development of creative methods with which to engage them.

A remaining shortfall for the inclusion of the views of children and young people, however, relates to qualitative research that is carried out alongside clinical trials including pilot, full trials or feasibility studies (feasibility studies are ‘pre-studies’ that, through a variety of different strands of data collection, assess the feasibility of carrying out a future full clinical trial). The value of using qualitative research with adults within, or alongside, randomized controlled trials (RCTs) is becoming more widely accepted (Cooper et al., 2014), with researchers such as Donovan, Mills, Smith, Brindle, Jacoby, Peters, Frankel, Neal & Hamdy, (2002) illustrating the transformative effects that can result when qualitative understandings are sought from patients and professionals to assist the design, conduct and

analysis of trials. Qualitative research can be incorporated before, during or after clinical trials, with a range of aims, shown in the list (taken from Lewin et al., 2009) below. It is important to state that whilst we use the term ‘qualitative research’ in this article, we do not see this as one single paradigm that is in opposition to quantitative research. Rather we see qualitative research as encompassing a range of methods, approaches and paradigms (Field, 2017), as is discussed more fully later (see, for example, Fig. 1). We nevertheless find Lewin’s categorization, in the list below, useful and would accept that research that seeks participants’ views, opinions and understandings (i.e. that is broadly ‘qualitative’) can enhance the design, conduct and interpretation of clinical trials research.

Purpose of Qualitative Research in Trials (Lewin et al. 2009, p.2)

Before a trial

- To explore issues related to the healthcare question of interest or context of the research
- To generate hypotheses for examination in the randomized controlled trial
- To develop and refine the intervention
- To develop or select appropriate outcome measures

During a trial

- To examine whether the intervention was delivered as intended, including describing the intervention as delivered
- To “unpack” processes of implementation and change
- To explore deliverers’ and recipients’ responses to the intervention

After a trial

- To explore reasons for the findings of the trial
- To explain variations in effectiveness within the sample
- To examine the appropriateness of the underlying theory

- To generate further questions or hypotheses

The policy precedent for involvement of children and young people set out above also holds true for research within and about RCTs. Children’s views and understandings should be taken into account when they are being asked to become involved in a trial which may

involve non-standard treatments with, as yet, unknown effects. Generally, however, they are not. The need to gather protocol-specific data, worries about children's capacity to understand complex concepts and make competent decisions, as well as uncertainty about the resources required are all possible deterring factors (Weil et al., 2015, Coad et al., 2008; John, Hope, Savulescu, Stein, & Pollard, 2008). Lewin et al. (2009) carried out a systematic sample of 100 trials published in English from the register of the Cochrane Effective Practice and Organization of Care Review Group between the years of 2001 and 2003. Of those, 30 included a qualitative element. Of that thirty, only one study engaged with young people (teen mothers), and none with younger children, below the age of 12. Since that date, few studies have been published that have attempted to include the views of children or young people in qualitative research, within (Lloyd & Wyatt, 2014) or about RCTs (Shilling, Williamson, Hickey, Sowden, Smyth & Young, B., 2011).

Speaking to the identified gap, this article focuses on the means of engaging children's perspectives in clinical trials research. We report on methodology at two interwoven levels in this article. On one level, we report on the approach involved in interviewing children (and their families), as a sub-section of a wider feasibility study (Duration of intravenous antibiotic therapy for children with acute osteomyelitis or septic arthritis: a feasibility study, HTA no:10/046/01: DINOSAUR study). At another level, we report on our method of planning, collaboration and reflection between the qualitative health researchers originally working on the clinical trials study and colleagues with expertise in the fields of early childhood and education research that has led us to a new understanding of the possibilities for researching children's voice in clinical trials. The collaborative method undertaken has resonance with Wickson, Carew and Russell's (2006) review of the challenges and principles in transdisciplinary research. It acknowledges the value of: 1. collaboration between research communities, 'What becomes important then is the ability of

the individual to fuse knowledge from a number of different disciplines and engage with stakeholders in the process of generating knowledge' (Wickson et al., 2006, p. 1052); 2. reflection, '... using different bodies of knowledge and their methodological approaches to critically reflect on one another in a transformative process' (Wickson et al., 2006, p. 1054). The steps undertaken in the two levels of methodology are discussed and followed by a critical review of the challenges and implications of engaging with children's perspectives in such studies.

This qualitative study, involving interviewing children and their families, could be located at points 1, 3 and 4 of Lewin et al.'s categorization above (Fig. 1) in that it set out to explore issues related to the healthcare question of interest or context of the research; to develop and refine the intervention and to develop appropriate outcome measures. Whilst this study was carried out in the context of clinical trials research, we believe it also holds relevance for health research more broadly, and research with children within other academic fields.

The qualitative research team was made up of two health researchers with extensive experience of qualitative methods (Qualitative lead - CB), experience of conducting qualitative research in pediatric settings and family homes (Research Fellow - AL), but without experience of engaging children directly as research participants. The team was enhanced by the involvement of an early childhood researcher (co-author, PL), with experience of using a variety of research methods to engage young children. Whilst PL was less involved in data collection than AL, she was instrumental in helping us to develop interview guides and prompt material for different ages of children and in recommending the use of toys and puppets with younger participants (see Clark 2005 for a review of such methods). Once data collection and analysis were completed, we undertook a process of reflection on the approach employed, engaging the expertise of JP.

As a Professor of Education (Early Years), JP has firsthand experience of conducting research with young children. For example, she has used digital ethnographic case study methodology in early years' settings and in homes, incorporating video, digital audio recording of children's naturalistic interactions and of situated discussions with children, and video-prompted informal interviews with practitioners, to foreground children's experiences and perspectives (Payler et al. 2015; Georgeson & Payler, 2015; Payler 2007, 2009). Through a series of discussions, we reflected on what we felt had worked well with our approach to interviewing children and families, as well as areas of remaining difficulty or dilemma. Some of these had been immediately apparent; others emerged with hindsight. JP's role in these discussions was to highlight approaches and learning from research in education, early years and childhood studies that we might usefully employ when seeking to address these dilemmas in any future work. These discussions enabled us to surface and reflect on the differing ontological and epistemological assumptions underpinning research within different disciplines, which in turn, inform and shape methodological approaches, each with strengths and limitations. These reflections are presented below, with reference to study data. We go on to suggest a theoretically-informed continuum of children's engagement in research, designed to help researchers consider the contextual and theoretical constraints of individual projects, and within that, the range of techniques that may be available to them.

Background to the Study

This qualitative study was conducted as part of a larger, mixed methods, study to investigate the feasibility of a future RCT to determine optimum duration of intravenous antibiotic therapy for children with acute osteomyelitis or septic arthritis.

In exploring the feasibility of a future randomized controlled trial (RCT) to identify optimum point of switch from intravenous to oral antibiotics in the treatment of osteomyelitis (OM) or septic arthritis (SA), it was critical that the views of affected children and their parents were

included in the data used to inform decision making. The overall purpose of the interviews was to explore children's and parents' views, understanding and experiences of both bone and joint infections and treatment, and willingness to participate in a future RCT. Our aims were:

1. To explore the experiences of children, and their parents, treated with intravenous and/or oral antibiotic therapy for bone and joint infection about their condition and understanding about treatment.
2. To identify which clinical outcomes are most important to young people, and their parents, with bone and joint infections, in order to contribute to the wider stakeholder Delphi and stakeholder consultation process.
3. To explore the views of children, and their parents, admitted to hospital with bone and joint infections about participating in a RCT, in particular focusing on:
 - a. information required in order to provide informed consent;
 - b. views about and acceptability of potential interventions;
 - c. willingness to be randomized to either arm (i.e. treatment or control) and
 - d. influences on the above factors.

Approach

A purposive sample of children aged birth to 16 years was identified from four of the seven centers in the South of England, who had participated in the main Dinosaur service evaluation and microbiology sub-study. The purposive sampling strategy addressed variation with regard to age, gender, and ethnicity.

The Inclusion criteria for interviews identified were:

- Parents and children from 3 months to sixteen-years-old, treated for osteomyelitis and/or septic arthritis;

- Children who had been treated for bone and joint infections at one of the seven sites participating in main service evaluation and microbiology sub-study;
- Parents/children who had taken part in the main Dinosaur study and consented to take part in this qualitative study.

Twenty six families were recruited to the study. The age distribution of children represented was as follows: birth-3 years = 10 children; 4-7 years = 5 children; 8-12 years = 4 children and 13+ years = 7 children. Children under the age of four were excluded from participating in interviews directly (although they were usually present whilst interviews were being conducted) due to their age. Eight children took part in research interviews, of which 3 were aged 8-12 and 5 were aged 13+. Interviews mainly took place at respondents' homes between January and March 2015. Three parent only interviews were conducted over the telephone due to issues of location and availability. The interviews were digitally recorded, with permission from the families and children. Ethical approval was obtained from the National Research Ethics Committee – NRES Committee Yorkshire & the Humber - Leeds West (14/YH/1166 September 2014). We conducted thematic analysis of the data (Braun & Clarke, 2006) .

We chose to use research *interviews* for a number of reasons. Firstly, septic arthritis and osteomyelitis are relatively rare conditions in children, and participants were widely spread geographically, and in age, making gathering together groups of children for peer-based focus groups almost impossible. The 'specific', and quite complex, nature of the data we were seeking also seemed less suited to more creative approaches such as arts or play based techniques, which we considered may work better for dealing with broader topics. We reflect on decisions relating to methods and the age of children's engagement further during the course of the article.

What worked well

Adapting interview to child's age and 'expressional style'

Children do not represent a homogenous group. Children's capacity to understand and express themselves develops with age and experience. This was a particular issue in this study, as the children treated for bone and joint infections ranged in age from new-born babies through to young adults.

As health researchers dealing primarily with adults, AL and CB did not possess expert understanding of child development (although this can of course be found in the academic literature, e.g. Gibson, 2012). We did, however, have our own personal experience of interacting with children of various ages in our roles of parent (AL) and aunt (CB), which Garbarino and Stott (1992) have identified as valuable in conducting research with children. To supplement this, we enlisted the help of a number of colleagues within the broader faculty, in particular working within Education and Early Years. A group of colleagues met together before data collection to discuss the proposed research approach and interview guides; in particular PL provided detailed guidance about the appropriate use of language register, attention span and ability to grapple with complex ideas according to the various ages of children we were hoping to approach. As a result of this, we developed three interview guides, with associated prompt material. Prompt material involved a process diagram of the proposed RCT and a list of potential benefits and risks associated with each of the trial arms.

- Young children up to the age of 7 – this interview guide consisted of simple questions about children's experiences and understandings, involving the use of a doctor glove puppet and a dinosaur toy (Clark 2005). Because of the complex issues involved, this interview guide did not include a section on the proposed RCT. As discussed below,

however, no children in this age group took part in interviews. This was primarily because parents did not wish to involve younger children in talking about an event that had often been upsetting and traumatic for them – an issue which is discussed further later.

- Children aged 8-12 – this interview guide involved simplified language, but did cover all the same topics as the adult guide, including seeking views about the proposed trial ('test').
- Young people aged 13 + and adult: the same guide was used for both young people and adults.

As well as tailoring data collection tools, we also sought to match the 'expressional style' of the child (Irwin & Johnson, 2005, p.826). This involved following children's preferences around whether they would rather be interviewed along with or separate from their parents, tailoring questioning to help children express themselves (for example using closed questions where necessary, going 'off topic'), and recognizing and responding to varying attention spans. At the beginning of each interview, AL (or PL) asked children if they would like to be interviewed with, or separately from their parents, and, if they would like to be interviewed separately, whether they would like to go first or second (reflections on this – and the process of 'assent' are included in the discussion). All but one of the children opted to be interviewed with their parents in the room. At times, this worked as two separate interviews (with various 'chipping in' from the other parties) and sometimes it evolved into one interview – with the researcher addressing different questions to the different parties present (in these cases it felt more like a focus group than a research interview). Flexibility was certainly key in this regard. Children also sometimes opted to leave the interview for a time (perhaps leaving the room, or engaging in a different activity in the room such as

drawing or playing on a phone), re-joining to answer further questions at a later stage. This combined with the presence of family pets, babies, toddlers, phone calls, doorbells, requests for food etc., all made for interesting research settings. At times, AL (more used to interviewing adults, who at least tend to sit still), felt anxious that the interviews would not be yielding the information required. Nevertheless, whilst seemingly somewhat chaotic, the adoption of these techniques yielded useful and insightful research data. We were impressed at the ability of the children (including younger respondents) to recall and describe their experiences of becoming unwell, being treated and their recovery from bone and joint infection, as illustrated by Tessy's (aged 9) recollections recounted below (pseudonyms have been used for all of the child respondents):

Extract from Tessy's (age 9) interview

Interviewer: ... "Can you remember how long you were on the medicine for when you got home?"

Tessy: "...I had to have one week off school but then I think I might have had the medicine for two weeks or something...I had it at six o'clock at night and eight o'clock in the morning.

Mum: "You had it three times a day, I remember going up to the school to give it to you at lunchtimes. So yes.

Interviewer: "Thank you, and can you remember what the doctors told you about what had been making you poorly Tessy?"

Tessy: "I think they said from my ear infection the bugs might have got into my blood and went down to my knee."

Children also exhibited thoughtfulness and comprehension of some of the more complicated ideas concerning the trial and randomization. Some expressed ideas that resonated by those given with adult respondents in other interviews. In the quote below,

Rebecca (aged 10) is expressing her distrust of the concept of randomization. Her view was shared (although expressed in different terms) by a number of adult respondents who feared that involvement in a trial, and the process of randomization, may threaten children's access to tailored treatment that best suited their individual needs. Her response also made us reflect on how we could in future, also include an explanation of 'equipoise' in our description of the trial process.

Extract from Rebecca's (age 10) interview

Interviewer: "Would you have liked to have taken part in this test? It doesn't matter, you can tell me honestly."

Rebecca (age 10): "Not really"

Interviewer: "Why do you say that?"

Rebecca: "Just the thought of a computer that doesn't know any of your details choosing what treatment you have, because it should be a computer, or a person, who knows all your details and if you've had stuff in the past what treatment you get. It's a bit different.

... ..I just think it's a bit risky."

Gaining assent and building rapport

A number of authors have highlighted difficulties experienced in gaining trust from children, which may make them reticent to share their experiences with researchers (e.g. Irwin & Johnson, 2005). In this study, we did not feel that children were reticent to engage with us - children appeared happy to share their experiences and often tried hard to read and process prompt information.

To ensure children were comfortable with the interview process, we sought their 'assent' to participate (equivalent to 'consent' in the case of adult respondents). This involved

them writing their name on a simplified set of statements about the research once the researchers had given a description about the project. The process of assent provides an opportunity for children to express their opinions and concerns about participation in research, providing them with a formal means to be included or excluded (Piercy, 2004). It is, of course, imperative that they understood, and were able to ask questions about the proposed study. To help with this, we gave a simple explanation on arrival and provided a child information sheet ahead of the appointment (and again at the appointment if required), which they could read if they wished. We also explained that their participation was voluntary, that they could withdraw from the research at any point, without giving a reason, and that the answers they provide would be confidential and not attributable to them personally.

As discussed above, we also followed children's stated preference about whether to be interviewed with, or separately from parents, which we discuss further below. Whilst this appeared to work well in the main, in a couple of cases where adults appeared to 'take over' the interviews, it may have been more fruitful to interview separately.

We suggest there were a number of reasons for the ease we experienced in this respect of gaining assent and building rapport. Whilst we had not met with these families before, this was not the first contact families and children had had with researchers from the Dinosaur project. Their first involvement had been whilst in hospital, when a research nurse had explained the broader study to them and asked if they would be willing to have some extra samples taken to contribute to the microbiology part of the study. Additionally, families were asked if they would be willing to be re-contacted at a later date about taking part in a research interview. Only those families who had agreed to be re-contacted were approached about participating in this study. Families also tended to associate us with the hospital and the medical team who had treated the child, and to whom they were (generally) grateful. In fact,

on several occasions the researcher had to explain that she herself was not a nurse or doctor, but rather a qualitative researcher, working with medics for this study. This suggests that association with known and trusted professionals can help build trust with children and their families and facilitate the interview process. Chantler, Lees, Moxon, Mant, Pollard and Fitzpatrick (2007) make a similar suggestion when considering recruitment to pediatric vaccine trials. Whilst association with known and trusted professionals was helpful, the fact that AL and PL themselves were not doctors or nurses, (and from a university rather than a hospital), also seemed to free respondents (parents in particular) from the burden of providing answers that would be 'acceptable' with professionals more closely involved with their child's case. For example, a number of parents needed reassurance that it was alright to give critical comments (e.g. 'I hope it's alright to say this..?' etc.). Whether the mere association with the medical team may have limited what respondents said is difficult for us to judge. However, many of the adult accounts in particular spoke at length about a difficult period of diagnosis, in which they perceived certain symptoms to have been missed and errors to have been made. This suggests that they did not feel inhibited in giving their interpretation of events honestly.

There has been some debate in qualitative research over the role that adult researchers should take when working with children (Gibson, 2012). Whilst not having reflected on it before the conversation with JP, AL had automatically adopted an informal style, which appeared to fit with research occurring in people's homes - a stance more akin to a friend who had gone round for coffee to talk about something specific, than a professional coming in to deliver an intervention, or complete a formally structured questionnaire. This fitted well with the naturalistic position of ethnographically informed research methods (Hammersley & Atkinson, 2007) and facilitated children sharing their thoughts with us. In a couple of

instances, we were told things that perhaps parents may not have shared e.g. forgotten follow up appointments and dad not liking the 'grumpy' male nurse!

Remaining dilemmas

Reporting conventions and 'quote-able' data

It has been acknowledged by previous researchers of children's views that data originating from interviews with children does not mirror that of adults, whose talk tends to include longer sections of narrative, uninterrupted by the researcher's voice. Interviews with children do not tend to result in these 'solid blocks of text' (Irwin & Johnson, 2005; Wilson & Powell, 2001), and are characterized by shorter sections, punctuated with talk from the researcher and asides. This was certainly our experience, and yielded an issue for the reporting and analysis of data, which we only noted with hindsight.

Transcribed passages of uninterrupted talk offer rich pickings for those illuminative quotes that can bring qualitative data alive. The absence of these from the children's transcripts, made the finding of pithy illustrative quotes (such as are used in traditional adult-focused reporting techniques) harder in the transcripts of the children's interviews. Because of this, the quotes used in the presentation and report originated mainly from adult respondents.

This was pointed out to us by the 17 year old PPI representative at the end of a presentation made at the study stakeholder day. She suggested that, as the quotes came mainly from the parents, the child voice was being less represented. This was a useful and valuable point. Contrary to the approach taken with data collection, we had been seeking to insert qualitative data from the children into the adult reporting paradigm. There is work to do in considering how such data can be best presented and reported more creatively by health

researchers, and it is important to consult PPI reps, and participants themselves, about how this might be done. Equally, it calls into question the appropriateness of relying solely on interview data when trying to examine and represent children's views on their health, illnesses and treatments. This is an area where qualitative health research can learn from other disciplines, and is discussed further below.

Differing perspectives of children and adults

Another un-anticipated issue arose in instances where children and adults expressed different perceptions, or gave differing emphasis, when reporting the same events. Whilst able to acknowledge the painful aspects of their illness and treatment, we noticed that on a number of occasions children appeared to downplay the impact of events on them, or to focus on different issues to their parents, whose accounts tended to emphasize the high levels of distress they and their child experienced. Some examples are shown below; as explained above, these extracts are somewhat extended, due to the nature of the data we gathered:

Extract from interview with Toby (10)

Researcher: So, I just wanted to ask you what it was like for you when you were having your antibiotics like this, through the line? (Referring to a picture of an IV line)

Toby: It kind of stung sometimes, but then sometimes it didn't even hurt at all and I just forgot about it.

Researcher: ...did you think there was anything good about having the antibiotics like this? (referring to picture of line).

Toby: Yes, they kind of made me feel better over like the few days.

Researcher: was there anything that wasn't very nice about having them like this?

Toby: Sometimes when it went through the tube it kind of stung a bit along the vein.

Dad, interjecting: *The first time they put it in, he was in agony and they had to stop it and take it out and redo it, because we weren't quite sure whether it was in a wrong vein or something. They tried different sites on the same arm...in the end they tried another site on the same arm and it was horrendous. He was...*

Toby: *Screaming.*

Dad: *He was like'Rip it out' [dramatic voice]...That's why (when) Toby was going 'it stung a little bit', I thought, hang on this is the boy that was sitting there going 'Rip it out!' [dramatic voice].*

In Toby's account, he has presented receiving the IV antibiotics as stinging a bit, whereas his dad has described it as agonizing. In another instance, of apparent 'downplaying' Tessy (9), talking about her admission to hospital, stresses her experiences of using a wheelchair (a theme she returned to several times during the interview), above the discomfort described in her mum's narrative.

Extract from interview with Tessy, 9

Mum: *And so then we went up to the children's hospital...*

Tessy: *I got my first wheelchair with the big wheels, and I kept bumping into walls [chuckles].*

Researcher: *Did they send you pretty much straight on then?*

Mum: *Yes, they did start explaining about the septicemia, but obviously they need to run tests. They couldn't do anything at the (local hospital), it's just like an outpatients - it's not like an A&E place.*

Tessy: *They told me to go to the (main hospital)*

Mum: *They did, didn't they? And I couldn't, and by that time, by the time I got into (location) she was saying she couldn't walk and I had to carry her. Which was why we got the wheelchair in the first place.*

Tessy: But when we went to the first one, I remember I had to wait on a wooden bench for a wheelchair... That was my first wheelchair. With tiny wheels.

Mum: Yes, that one was because your leg was sore and you were tired. But yes, by the time we got to the children's hospital she was finding it really painful to even stand, like put any weight at all on her legs.

In another instance, Charlotte (13) talked about receiving a general anesthetic – the extract highlights the difference in experience of child and parent.

Extract from Interview with Charlotte (aged 13)

Researcher: So you had to have a general anesthetic?

Charlotte: I think so.

Mum: Yes.

Researcher: What was that like mum?

Mum: That's not nice is it?

Charlotte: I was fine.

Mum: She's all right, anything.

Researcher: I was thinking about mum – I bet she was more worried than you?

Mum: It's worse for the parents watching...

Charlotte: Why? Dad cried, I was like, 'What are you doing?'

In the third extract from Charlotte, it is clear that she was less distressed by the incident than her parents were. In the previous two extracts children present more pragmatic accounts of events, with parents tending to focus most on the level of distress they perceived in their child. Wilson and Powell (2001) show us that children may focus on different issues as an event takes place (illustrated by Tessy's fascination by the wheelchair), and that this affects how they store and present their memories. In hindsight, we reflect that as adult

researchers, our analysis afforded greater weight to the descriptions given by parents about events and that we tended to see children to be 'downplaying' the seriousness of events for the sake of the interview. Thus, we took from Toby's extract that his initial experience of having the IV cannula inserted was highly unpleasant, even though this is not how he initially describes it. We understood from Tessy's mum that the child was poorly and in a lot of discomfort, even though Tessy herself focuses more on experiences with various wheelchairs. Despite these interpretations, it is possible that parents' heightened levels of anxiety during the time of their child's illness may have led them to overstate the discomfort and risk associated with their child's condition (thus making children's accounts in fact more 'accurate'). The recognition of these differing perspectives, and how we may take them more fully in to account is revisited later.

Gatekeepers and a risk of paternalism?

Linked to this, was the issue of protective feelings that arise in adults when considering talking to children about events that they may have found upsetting and unpleasant. As described above, parents of children up to seven were reticent to involve them in interviews about their experiences of being ill. As a parent herself, this felt completely understandable to AL, who did not at any stage question this decision on the part of parents. Similarly, during the interview process, there were a number of points when AL felt uncomfortable at asking children (and indeed parents) to go over events in cases where children had been particularly unwell or upset. In one interview, a teenage girl and her mum described their frustration and sadness at the failure of treatment, such that the child's infection had become a chronic, persistent and debilitating problem. In this interview, AL did not feel she could show the prompt materials relating to antibiotic therapy – feeling that she did not want to introduce any more potential worries by highlighting a list of potential risks of prolonged antibiotic therapy. In some ways, this resonates with the findings of Donovan, Paramasivan, de Salis and

Toerien (2014) who found that in recruiting to clinical trials, medics may exclude inviting particular patients for a variety of protective reasons.

Of course, issues of empathy, and attending to the feelings of respondents are paramount in qualitative research. However, the role of these protective feelings was questioned by our insightful PPI representative, who suggested that whilst adults may feel that children will not want to talk about something, or that a particular set of information may trouble them, we do not really know this to be the case until we ask them. This was food for thought, particularly in light of the findings discussed above in relation to the differing interpretations of children and adults about events. It was further illustrated by an exchange between a mum and her 15 year old whose condition had made him critically ill.

Mum : "You've moved on better than I have."

Sebastien: "Yes, it happens, can't do anything about it now, that's my way of looking at it."

Mum: "That's a very good way. That's a very healthy way."

Whilst certainly not seeking to downplay the need to conduct research in an ethical and considerate way, this suggests that sometimes our own feelings as researchers, may limit the data we collect from children, who may be more resilient than we think. Here again, we suggest that involving children as PPI representatives during the design phase of the study would help us to get a better understanding of when we are being rightly cautious and when we may be becoming 'overprotective', thus limiting the potential for children to be heard. It would also be worth considering here the issue of whether it may be preferable for children to be interviewed on their own (separately from their parents) if they are old enough (although what constitutes 'old enough' and who decides is also contestable). In this study, the presence of the parents with the child did influence the course of discussions, with interactions happening between children and parents in the context of the interview. In this way,

interviews became at points more like a focus group, which can have strengths as a method of data collection with children (Gibson 2007; Horner 2000; Morgan et al. 2002). Whilst this may have stimulated new and different ways of thinking, it is possible that children may have felt freer to present their accounts in their own voices, outside of the presence of their parents. This must be weighed against confidence of children to talk to researchers independently of their parents' support.

Discussion

Key methodological issues and dilemmas were surfaced during the joint critical reflection between the authors. These have been flagged for attention throughout the article and include:

- ethical considerations (assent, the role of gatekeepers) and links to the quality of research data
- methods beyond interviewing for collecting data and tools for reporting/analysis that allow space for children's views to be heard.
- the quality of researchers' interview skills, drawing on their interpersonal qualities, and the implications for training;

Each of these will be considered shortly and contribute to our suggested interdisciplinary framework for moving the field of health and illness research with children forwards. However, before that, we suggest that there are fundamental deliberations necessary with regard to where health research positions itself in relation to children's perspectives because something more than developing or appropriating research tools is required to enable the field to avoid token voices. Such deliberations contribute to Weil et al.'s 2015 call for further progress in children's voices being listened to, their needs understood and rights respected.

Children's engagement in research more broadly to date might usefully be conceptualized as a continuum ranging from children being empowered and trained to

undertake research of their own choosing to children's views or responses being sought in relation to strictly adult-defined questions by means of adult-oriented methods (see fig 1 below: continuum of children's engagement with research, Payler 2016).

Figure 1: Continuum of children's engagement with research (Payler 2016)

<Child -----< Locus of decision-making ----->-----> Adult>

Approach	Children as researchers	Children as co-researchers with adults	Children as participants in 'open-ended research' by adults	Children as expert reference groups to adult-led research	Children as participants in 'closed-purpose research' by adults
Outline	Children are usually trained in research methods by adults; Children set own research agendas (within parameters of adult guidance, depending on age/experience of children); Children use own research processes to conduct own research studies; Children report on own research findings; Adults as facilitators for child-researchers.	Children co-construct research agendas and questions with adults; Children contribute to determining research methods; Children are key researchers and research participants, seeking and contributing to data; Children may contribute to presentation of findings; Alternatively, children may be involved in selected stages of the research process; Adult/child research facilitated throughout by adult co-researchers.	Exploratory research by adults with aim of eliciting matters of importance to children within broad themes and children's perspectives on them; Adults use children's perspectives to further shape research questions; Adults seek ways to give 'voice' to children's experiences through multiple methods; Adult researchers seeking to research children's experiences sensitively.	Child reference groups are consulted to influence adult research agendas; Children comment on appropriateness of methods, findings and reporting procedures; Adult researchers seek guidance, trialing and legitimization for their research from children.	Adult sets research agenda, questions and approach; Children's views or experiences are sought as data on closely defined topics or questions within tightly controlled inclusion/exclusion parameters; Adult researchers seek reliable and valid data from children where children are the source of data rather than the generators of data.
Epistemological and ontological underpinning	Reality is socially-constructed in that it is multi-voiced and multi-perspectival; Children as experts in their own lives (but not in other children's lives).	Reality is socially-constructed in that it is multi-voiced and multi-perspectival; knowledge is co-constructed in dialogic manner between adults and children.	Reality is socially-constructed in that it is multi-voiced and multi-perspectival; knowledge is constructed through adults seeking out and sharing multiple perspectives, including children's.	Reality exists and can be uncovered. Children's experiences can add to knowledge of that reality if and when their participation is considered reliable and trustworthy.	Reality exists and can be uncovered. Data from children's experiences can add to knowledge of that reality if and when their participation is considered reliable and trustworthy.
Potential strengths of the approach	Children determine what is important to research, which could be different from adults' views; Children carry out the research in ways that are meaningful for them; Full engagement in the research	Keeps close to children's experiences, but partially shaped by adult facilitation, so can mesh adult and child concerns; Adult researchers incorporate children's perspectives into the	Keeps close to children's experiences; Approach can be more inclusive of perspectives of very young children or those with less capacity for independent	Gives scope for children to influence some aspects of research design or methods within limitations, potentially offering previously unthought-of perspectives.	Uses pre-determined protocols to study specific research question(s) from pre-determined approach; Allows control to be retained over features deemed

	process could empower children's participation; Children may feel full ownership of the project and its findings.	entire research, but adult co-researchers are more likely to contribute to maintaining the rigor of the research project.	communication and action; Approach is not reliant on verbal articulation or children's capability to carry out research themselves; Adult researchers incorporate children's perspectives, but maintain the rigor of the research project		important to research aims; Adult control maintains rigor of the research project.
Potential weaknesses of the approach	Could exclude children who have less capacity for independent communication and action; Topics for research could be constrained by those topics children feel sufficiently comfortable and skilled to research, further limited by adult facilitation of what is considered 'suitable and safe' for children to research; Research training might lead to children being supported to conduct research in ways that adults construct for them, leading to socialization rather than empowerment.	Could exclude children who have less capacity for independent communication and action, although this will be facilitated by adults; Topics for research could be constrained by those topics adults consider 'suitable and safe' for children to research in collaboration with adults.	Open-ended nature of research could mean that specific findings considered to be of use to policy or practice are not arrived at or are not taken up.	Reliant on selected children 'representing' other children's views, which could be questionable; Could exclude children with less capacity for independent communication and action, including very young children.	Could exclude previously unthought-of perspectives, questions and agendas; Prioritizes adult perspectives over children's experiences; Could adopt a deficit view of young children's capacity for contributing meaningfully to research, thereby restricting access to meaningful data through limited methods; Reliability through adult control could be at the expense of validity where genuine access to children's authentic perspectives and experiences is not obtained, depending on researcher skill and exact methods adopted.

Note: Approaches outlined are indicative points along the continuum, but do not comprise its entirety. 'Children as researchers' alone encompasses many variations, see for example Kim, 2015.

Different locations along the continuum imply different underpinning epistemologies and conceptions of children and are often associated with different research paradigms (some of the epistemological and ontological debates are discussed in Kim, 2015) as well as methods. Different locations along the continuum are also implied by the *nature of the research questions* under investigation as well as by *who determines* the research questions or indeed the research agendas. We suggest that by surfacing these different approaches to children's engagement in research and the associated implications for agenda, methodologies and design, new possibilities for qualitative health research with children may be considered. Clinical research historically operates from a paradigm in which carefully defined and bounded research protocols are determined by professionals according to scientific principles to answer specific questions necessary to further knowledge and treatment. Thus, it appears to fit more closely to the right-hand end of the continuum. This end of the continuum can be associated with the realist approaches, where 'reality' is seen as having an external existence of its own – however ambiguously represented - that can be uncovered through the research process and intellect of the researcher (Hollway & Jefferson, 2000). In such approaches, children's perspectives may be side-lined in favor of the more factually 'accurate' impressions of adults, or at least sought according to tightly defined criteria. Other positions along the continuum might offer further openings to enhancing health and medical research. At the left hand end of the continuum, the freedom and empowerment accorded to child researchers has the potential to open the way for their views, perspectives and priorities to be valued equally to those of their adult counterparts, although this claim is not without critique (see for example Kim, 2015). We can draw a parallel here to

constructivism's (Guba & Lincoln, 1989) recognition of the value of differing perceptions of 'reality'. As (Woodgate, 2001, p.149) writes:

"When children are viewed from an alternative perspective, the major principles of the qualitative paradigm may actually serve as facilitators to apprehending their thoughts and feelings. The following key principles of the qualitative research paradigm are... (a) realities are constructed by human beings who are viewed as active agents making sense out of the realities they encounter; (b) realities are multiple and must be perceived holistically and from various vantage points; and (c) realities are shared and mutually shaped by the researcher and research participants."

It is important to note, however, that positions at the far left of the continuum are likely to be most accessible to children whose learning, experiences, development or culture facilitate receptiveness to research training and competence to carry it out, such that it could exclude very young children or those with communication or learning difficulties or disabilities. In this case, children as 'open-ended research participants' may be the more liberating and inclusive approach.

Although children are already part of influencing aspects of practice through the PPI movement (e.g. NIHR Medicines for Children Research Network 2011, 2013), the left-hand side of the continuum might still seem a little far-flung for illness and treatment research, particularly with younger children. Whether or not such positioning seems feasible and helpful depends in part on how children are seen with regard to their competence and reliability in reporting on their own lives (see for example Kellett, 2005; Woodhead and Faulkner, 2000) and the value placed on their viewpoints. While patient experiences through the PPI movement are opening up new ethical concerns and agendas, leading to debate around the primacy of previously seemingly unimpeachable medical principles (for example in end-of-life care), the voices of younger children are still less evident in health research, although these too may open up new research questions and agendas. Positioning on the continuum also depends on the purpose of the enquiry undertaken and the questions it seeks to answer.

It is clear that finding out how to gain children's perspectives in qualitative health research, in addition to practical consideration of methods and tools, involves deeper epistemological and methodological deliberation. We suggest that through engaging in interdisciplinary research between health researchers and those experienced in educational or childhood studies research with children, a new space might be arrived at for children's perspectives in and for medical research.

We now turn to some of the specific issues already raised through this collaboration:

Ethical considerations (assent/gatekeepers) and the quality of research data

Ethical issues were raised during the conduct of the research reflection with regard to *how* to conduct research with children that allowed for and facilitated their willing and informed participation, and how and when to seek their assent. Such issues have an impact on the

quality and authenticity of data obtained. What are the implications of asking children if they would like to be interviewed alone or for their parents to be present when their parents are present while that question is asked? Some children will feel that it implies they have something to hide if they state they do not want parents to be present; some will feel more relaxed with parents present; others may want parents present but temper what they then say during the interview to save parents' feelings or to save face themselves. Decisions about access, privacy and assent impact on the quality of the data subsequently generated.

Christensen and Prout (2002: 490) set out a summary of key questions to address when considering ethical symmetry in research with children which could be used to ensure ethically-appropriate qualitative health research with children.

Methods beyond interviewing: research design and tools for collection and analysis

Some of the difficulties encountered in eliciting children's perspectives and experiences of health, illness and treatments, particularly but not exclusively those of the youngest children, pertain to the limitations of one-off, time-limited interviews conducted by a researcher with prompts largely based on verbal articulation or written material. Such methods have distinct limitations and it would be worth considering other methods, some of which are discussed by Clark and Moss, 2011:

1. Prompts using audio-recorded chat-and-walk tours of the facilities linked to the episodes of illness and treatment (Clark and Moss, 2011: 28-29) (could be virtual using a video recording of the facilities, using loose photographs or comic-strip style)
2. Discussions based around reviewing sets of photographs;
3. Giving children cameras to take photographs of their experiences and then tell their story / discuss them (Clark and Moss, 2011: 23-27).

4. Engaging views over time, e.g. by sending back an audio podcast of the researcher telling the 'story' of what the child told the researcher and inviting the child to add extra comments as they think of them to a digital voice recorder or video blog;
5. Giving children [and parents] questions and prompts in advance so that they have time and opportunity to think about their responses and add to them over time, preferably digitally.
6. Video-recording of informal interviews, [virtual tours] and discussions to enable deeper and more sensitive analysis of the child's responses, particularly the non-verbal features of communication.

Similarly, creative approaches to the development of prompt materials for younger children is required. It is important to also give thought to how the findings from these and more traditional methods will be analyzed and presented to ensure that children's views are accurately interpreted and heard (Punch, 2002). We suggest that consideration as to the outputs of the research are included at the design stage, with due consideration made to the requirements of the each research study. Ethically, it may be important to think about how children might understand and accept the role their views will have – for example, where children are involved in service re-design, it may be reasonable for them to see direct implementation of their suggestions, while in other instances, this is less likely. This sits alongside broader debates about the role and purpose of qualitative research alongside clinical trials (Cooper et al. 2014).

It may be assumed that once data are collected, the task of analysis is likely to be beyond the participation of children, particularly younger children. However, Lundy, McEvoy and Byrne (2011) provide a useful example of how preparing for children's involvement *with children* prior to data collection and involving children during analysis can

enhance the quality of the research and its findings. For example, framing their research within a children's rights perspective, Lundy et al. (2011) explain how they used workshops with visual and kinesthetic methods in advance of the data collection phase of their research with four- and five-year-olds to introduce the children to 'the broader concepts in which the research study was situated' (Lundy et al. 2011: 721) so that the children could engage more fully with the purpose of and substantive issues related to the research, thus facilitating their participation as co-researchers and having a direct impact on the validity of the findings. Lundy et al. (2011) also explain how they engaged the four- and five-year-olds in the analysis of their co-researched data through finding visual ways to represent the study results meaningfully and then using these to facilitate discussion.

'In sum, although the picture survey highlighted what children liked or found difficult, it did not always tell us why this was the case. The [child co-researchers] were able to provide expert perspectives that enabled us to gain insight and understanding into the reasons underlying the responses' (Lundy et al., 2011:727).

Such approaches are indicative of the range of ways in which research with children can be analyzed, enriching findings and interpretations. Insight may also be afforded from narrative techniques for analysis and related, psychodynamically informed work e.g. Hollway & Jefferson (2000), which acknowledge that responses and impressions given by research subjects are likely to be subject to a range of conscious or unconscious influences, such as the need to defend against particularly anxiety provoking or emotionally intense experiences. In these interviews it may have been helpful to consider influencing factors that could have shaped children's (and adults') responses to questions about their experiences (for example, downplaying to make the situation feel more manageable, not wishing to upset parents by showing their own distress at events and so on).

Quality of researchers' interpersonal/research skills

The most elegant and open research tools might be inadvertently operationalized in different ways by the mediation of different researchers; no two interviews are really the same when undertaken by different researchers. There is more at play in gaining and maintaining genuine participation of children than an association with known/trusted doctors or nurses. To engage children in genuine and open participation, with children being willing and able to access, recall and reveal their feelings and memories about illness and treatments, requires interpersonal skills that are sensitive and responsive to the child as an individual and to his or her context. There are clearly implications for selection, training and personal development of researchers for such tasks as well as for developing appropriate research tools.

Conclusion

In this article, through critical reflection on the two inter-woven levels of methodology - researching children's perspectives on clinical trials and collaborative engagement with researchers from disciplines beyond health - we have presented a new model for planning, collaboration and reflection to advance the field of qualitative health research in relation to children's voice in clinical trials. We described how the context within which a study was carried out set parameters around the methods chosen to collect and report our data and, as a result, raised some issues as to how accurately children's perspectives were heard and reported. For researchers operating within the health field, there is great value in explicitly acknowledging and defining the constraints of context and of ontological and epistemological positioning. Such an exercise would provide a starting place on the presented continuum of engagement. However, rather than adopting a fixed point, by considering approaches and perspectives of childhood researchers from disciplines with a broader range of approaches, and by engaging wholeheartedly with children and young people's PPI representatives, a

wider array of methods for collection and analysis become available, with the potential to take heed more closely of children's views and perspectives. Such potential could open up clinical research to more authentic findings about what matters to children and why.

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